

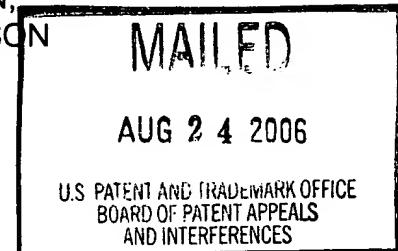
The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte TIMO NILS-ERIK LOVGREN,
ANTTI J. IITIA and KIM S.I. PETTERSSON

Appeal No. 2006-0308
Application No. 08/487,623



ON BRIEF

Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 6, 7, 10, 13 and 16-18. Claim 13 is representative of the subject matter on appeal, and reads as follows:

13. In a biospecific assay method comprising

- reacting microparticles coated with a bioaffinity reactant A which specifically binds at least one analyte to be assayed, a sample to be analyzed, and a labeled bioaffinity reactant B to cause said analyte and said labeled bioaffinity reactant B to specifically bind to said microparticles via the bioaffinity reactant A; and

- measuring signal strength from labeled bioaffinity reactant B bound to the microparticles to determine the analyte concentration of the sample, the improvement comprising:
- contacting a predetermined amount of said sample, a predetermined number of uniformly sized microparticles coated with said bioaffinity reactant A and said labeled bioaffinity reactant B labeled with a luminescent label such that, after the specific binding of the analyte in the sample to said predetermined number of uniformly sized microparticles, each individual microparticle emits a signal strength that corresponds to the analyte concentration in the sample, and
- measuring the signal strength from an individual microparticle using a measuring means capable of reading the luminescence from an individual microparticle and determining the analyte concentration in the sample by comparing said signal strength measured from said individual microparticle with a standardization curve, wherein said standardization curve is a mean of the signal strength of said predetermined number of uniformly sized microparticles.

The examiner relies upon the following references:

Soini	5,028,545	July 02, 1991
Buechler et al. (Buechler)	5,089,391	Feb. 18,1992

Ekins et al. (Ekins) "Multianalyte Microspot Immunoassay – Microanalytical 'Compact Disk' of the Future," Clinical Chemistry, Vol. 37, No. 11, pp. 1955-1967 (1991).

Bush et al. (Bush), "Solid-Phase time-Resolved Fluorescence Detection of Human Immunodeficiency Virus Polymerase Chain Reaction Amplification Products," Analytical Biochemistry, Vol. 202, pp. 146-151 (1992).

Claims 6, 7, 10, 13 and 16-18 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of

the claimed invention. In addition, claims 6, 7, 10, 13 and 16-18 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that appellants regard as the invention. Finally, claims 6, 10, 13 and 16-18 stand rejected under 35 U.S.C. §103(a) as obvious over the combination of Soini and Ekins, and claim 7 stands rejected under 35 U.S.C. § 103(a) as being obvious over the previous combination as further combined with Bush. After careful review of the record and consideration of the issues before us, we reverse all of the rejections of record.

DISCUSSION

Claims 6, 7, 10, 13 and 16-18 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

According to the examiner:

It is unclear how the claimed invention differs from routine optimization in determining a “predetermined” amount of affinity microparticles and sample volume which would not spread the bottom end of analyte concentration over so large a surface area as to render bound analyte-specific label indistinct from non-specific background label binding.

Examiner's Answer, page 4.

Appellants argue that the “rejection is not supported by proper reasoning or evidence.” Brief on Appeal, page 10. We agree, and the rejection is reversed.

The examiner argues that “[t]he issue is NOT whether one of ordinary skill in the art would be able to measure an individual microparticle as of January 18, 1994,” but “how the instant ‘predetermination’ of affinity microparticles and sample differs from routine optimization.” Examiner’s Answer, page 8. Thus, the examiner concludes “because appellants argue that ‘predetermination’ is not mere optimization, the subject matter of the instant claims do [sic] not appear to be described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Id.

It is unclear why the examiner is objecting to the language “predetermined,” as “predetermined” in the context of the claim would be construed as a known amount. If the issue is that the claims read on routine optimization, that would be more properly addressed in an art rejection.

It appears, however, that the examiner’s primary concern is that the disclosure as filed does not provide written description support for the language “a predetermined number of uniformly sized microparticles coated with said bioaffinity reactant A.” The disclosure, however, teaches at page 11 that the “number of microparticles has been checked by counting.” Specification, page 11. Thus, we find that the disclosure as filed provides support for that phrase.

Moreover, based on that section of the specification, we construe “a predetermined number of uniformly sized microparticles coated with said bioaffinity reactant A” as a known number of microparticles. That construction is supported by appellants, as they state “[i]n the present invention, an amount of micropartcles is used that is exactly known, i.e., predetermined.” Supplemental Appeal Brief, page 9.

We therefore find that the subject matter was described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and the rejection is reversed.

Claims 6, 7, 10, 13 and 16-18 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that appellants regard as the invention.

According to the Answer:

Claim 13 is unclear as to what criteria are used to “predetermine” the amount of microparticles and sample so as to correlate measurement of a single microparticle to analyte concentration, i.e., how does the “predetermined” amount of microparticles and sample volume of the improvement step differ from the microparticle and sample volume of the preamble of the Jepson claim. Measurement of analyte concentration from the signal measured from a single microparticle implies a critical relationship between the amount of sample analyte concentration expected in a predetermined volume of sample and the amount of affinity microparticles used. Critical limitations should be positively stated not merely implied.

Examiner’s Answer, page 4.

It is unclear to the panel what the examiner is objecting to. If it is the definiteness of the term "predetermined," as stated above, "predetermined" is construed to be known, and we thus do not find the term "predetermined" to be indefinite.

If the examiner is arguing that one skilled in the art would not be able to determine the correct predetermined, *i.e.*, known, amount, that rejection would be more properly made under 35 U.S.C. 112, first paragraph, on the grounds that the specification does not enable one skilled in the art to practice the claimed invention. The examiner has provided no basis for concluding that the specification does not enable one skilled in the art to practice the claimed invention.

As noted by appellants, their "invention is the discovery that the analyte concentration in a sample can be measured from the surface of a single microparticle by adjusting the relative amounts of microparticles and sample."

Brief on Appeal, pages 7-8. In addition, the specification teaches that:

The amount of the microparticles used in the assay, coated with the analyte-specific antibody or bioaffinity reactant as well as the amount of the analyte per microparticle will be adjusted so that a minimal concentration and volume of the analyte will contain enough analyte for binding to the surface of individual microparticles, and enough for measurement from individual microparticles by means of a labelled specific antibody (labelled bioaffinity reactant) and with the sensitive label technology used. The measurement range required and the sensitivity of the measurement will be controlled by adjusting the amount of microparticles used in the assay and by adjusting sample volume, if needed.

Id. at 9.

Finally, in the written description rejection above, the examiner states that “[i]t is unclear how the claimed invention differs from routine optimization in determining a ‘predetermined’ amount of affinity microparticles and sample volume which would not spread the bottom end of analyte concentration over so large a surface area as to render bound analyte-specific label indistinct from non-specific background label binding.” If it is the examiner’s view that the claim reads on “routine optimization,” it is unclear as to why the skilled artisan would not understand the scope of the claimed invention.

Claims 6, 10, 13 and 16-18 stand rejected under 35 U.S.C. §103(a) as obvious over the combination of Soini and Ekins, with 7 standing rejected under 35 U.S.C. § 103(a) as being obvious over the previous combination as further combined with Bush.

Soini is relied upon for teaching “high detection sensitivity biospecific assay methods using time-resolved fluorescent tracers and microparticles coated with analyte specific bioaffinity reactants using flow cytometry and microfluorometric measurement systems.” Examiner’s Answer, page 5.

According to the examiner, Soini fails to disclose the “basic concepts used to optimize biospecific assay methods, e.g., the interrelationship between sample analyte and assay reactants used to provide maximal sensitivity as instantly claimed such that the concentration of an analyte in a predetermined, clinically relevant range of analyte can be determined by measurement of signal from a surface of a single microparticle.” Id.

Ekins is cited for teaching "that all immunoassays rely on the measurement of antibody (i.e., bioaffinity reactant A) occupancy by analyte," and that when "the amount of antibody is vanishingly small, fractional antibody occupancy is independent of both the amount of antibody concentration and sample volume." Id. According to the examiner, "[w]hile Ekins [] exemplifies adjustment of antibody concentration and sample, i.e., analyte, concentration to optimize a microspot immunoassay, Ekins [] explicitly comments on the generic applicability of the teachings therein (see the entire article)." Id.

Bush is cited for teaching the application of fluorescent time-resolved microparticle based assays to hybridization assays. See id.

The examiner concludes:

Therefore, minus a showing of unexpected results, it would have been obvious to combine the generic optimization procedure of Ekins [] school in any given biospecific assay method, such as the fluorescent labelled microparticle based assay of Soini [] or Bush [], in order to obtain maximum sensitivity and/or minimize random errors as suggested by Ekins []. In addition, one of ordinary skill in the art would have considered at least the following factors in optimizing a given biospecific assay: the expense of bioaffinity reagents, the clinically (or otherwise) significant result range, the type of sample being assayed, the specificity and affinity of the bioaffinity reagent for analyte, the desired time to result, etc.

Id. at 5-6.

Appellants argue that the examiner has failed to set forth a prima facie case of obviousness. Brief on Appeal, page 13. We agree, and the rejection is reversed.

"A rejection based on section 103 clearly must rest on a factual basis, and these facts must be interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, all facts must be considered. The Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis. To the extent the Patent Office rulings are so supported, there is no basis for resolving doubts against their correctness. Likewise, we may not resolve doubts in favor of the Patent Office determination when there are deficiencies in the record as to the necessary factual bases supporting its legal conclusion of obviousness." In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. Denied, 389 U.S. 1057 (1968) (emphasis in original).

As noted above, we have construed "a predetermined number of uniformly sized microparticles coated with said bioaffinity reactant A" as knowing the exact number of microparticles present. As none of the references relied upon by the examiner teach or suggest that limitation, the rejection fails to set forth a prima facie case of obviousness, and the rejection is reversed.

CONCLUSION

Because the examiner failed to set forth a prima facie case of unpatentability, all of the rejections of record are reversed.

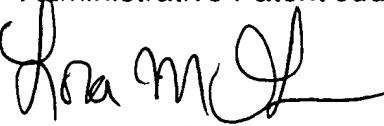
REVERSED

Demetra J. Mills

Demetra J. Mills
Administrative Patent Judge

Eric Grimes

Eric Grimes
Administrative Patent Judge

Lora M. Green

Lora M. Green
Administrative Patent Judge

) BOARD OF PATENT

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